

INSTRUCTIONS FOR USE

Rusfertide (PTG-300) for injection, for subcutaneous use

This "Instructions for Use" contains information on how to prepare and inject PTG-300.
If you have questions about how to prepare and/or inject PTG-300, please contact your Clinical Site.

Important Information You Need to Know Before Injecting PTG-300

- **Read all the below instructions for use before beginning the preparation and injection of PTG-300.**
- Use only the supplies provided with the drug kit.
- **Do not** use if the kit is expired or if any of the supplies are opened, damaged or missing. Contact the Clinical Site.
- Remove the kit from the refrigerator at least 15 minutes before you start preparing to allow it to warm to room temperature.
- You will need a Sharps Container and alcohol swabs (provided by Clinical Site) in addition to your drug kit, each time you inject.
- **Do not** touch the gray rubber stopper on the top of the vial.
- **Do not** let the syringe tip or needle touch your hands or any surface.
- Inject drug within **4 hours** of mixing it.
- For subcutaneous injection only (inject directly into the fatty layer just under the skin).
- Refer to the Disposing of Rusfertide (PTG-300) section on how to properly dispose of or return used supplies from the kit, including safe handling. All supplies are for single use only.
- Return unused drug vials to the clinical site.

Storing PTG-300 Before Use

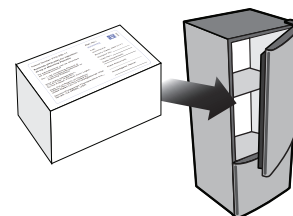


Figure A

- Store the PTG-300 kit in the refrigerator (2° to 8°C / 36° to 46°F) (Figure A).
- **Do not freeze.**
- **Keep out of reach of children.**

Step 1: Getting Started

1.1

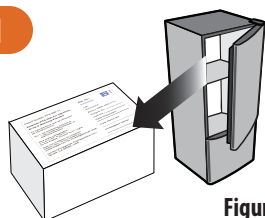


Figure B

- Remove the kit from the refrigerator at least 15 minutes before you start preparing the dose (Figure B).
- Place on a clean flat surface and **let it sit for at least 15 minutes** to allow it to warm to room temperature.

1.2



Figure C

- Wash hands with soap and water (Figure C).

1.3

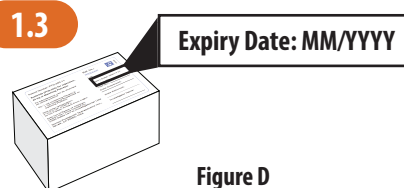
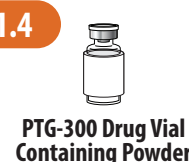


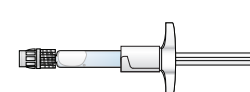
Figure D

- Check the **expiration date** on the outside of the kit's carton (Figure D).
- Check if the supplies have been **opened, damaged or missing**.
Do not use if the kit is expired or if any of the supplies are opened, damaged or missing. Contact the Clinical Site.

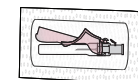
1.4



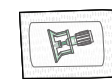
PTG-300 Drug Vial
Containing Powder



Prefilled Diluent Syringe



Needle



Vial Adapter

Figure E

- Confirm all supplies are in the kit (Figure E). Remove items from the kit and place it on a clean flat surface.

Note: In addition to the items that come in the kit, you will also need Alcohol Swabs and a Sharps Container provided separately (Figure F).



Alcohol Swabs



Sharps Container

Figure F

Step 2: Reconstituting Rusfertide (PTG-300)

2.1

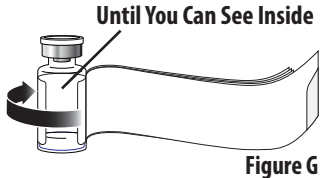


Figure G

- Peel back the label all the way. You should be able to see inside the PTG-300 drug vial (Figure G).

2.2

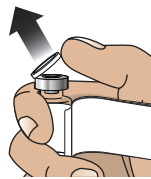


Figure H

- Remove the cap from the PTG-300 drug vial (Figure H). Throw away the vial cap.

2.3



Figure I

- Clean gray rubber stopper on top of PTG-300 drug vial with a new alcohol swab (Figure I). Throw away used swab.
Do not touch the gray rubber stopper on the top of the vial with your hand after cleaning.

2.4

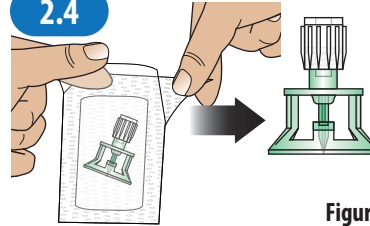


Figure J

- Remove the vial adapter from its package (Figure J).
Do not touch adapter spike or place it on a surface.

2.5

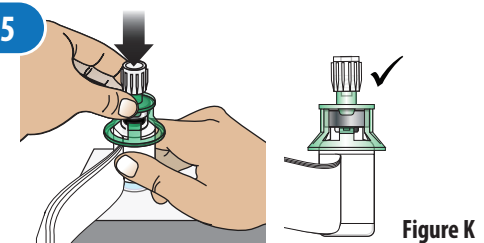


Figure K

- Push the adapter straight down onto the top of vial until it snaps on and is fully attached (Figure K).
Do not attach the vial adapter at an angle.
Note: The spike on the vial adapter should punch through the gray rubber stopper.

2.6

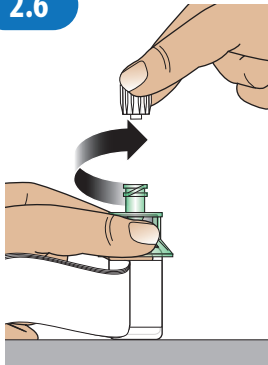


Figure L

- Remove the vial adapter cap by holding the vial adapter with one hand, and with the other, unscrew the cap by turning counter-clockwise/to the left until it lifts away (Figure L). Throw away the vial adapter cap.
Do not touch the vial adapter tip.

2.7

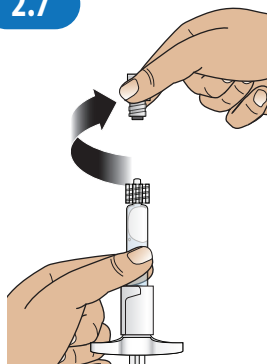


Figure M

- Unscrew the cap from the prefilled diluent syringe by turning counter-clockwise/to the left until it lifts away (Figure M). Throw away the syringe cap.
Do not touch the exposed tip of the prefilled syringe.

2.8

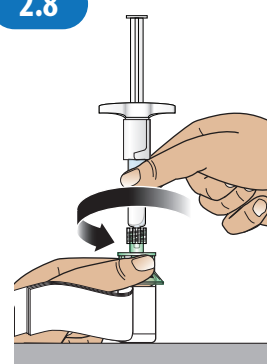


Figure N

- Attach the syringe to the PTG-300 vial adapter by holding the vial and screwing the syringe onto the vial adapter by turning clockwise/to the right until you feel resistance (Figure N).
Do not overtighten.

2.9

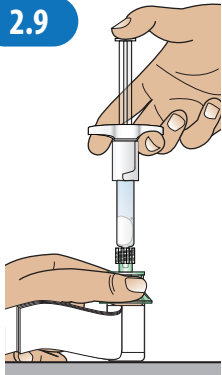


Figure O

- Inject the diluent into the drug vial by **slowly** pushing down on the syringe plunger until fully depressed (Figure O).

2.10

Swirl Slowly for 60 Seconds

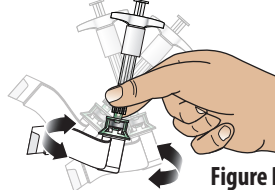


Figure P

- Mix the diluent and drug by slowly and gently swirling the drug vial **for at least 60 seconds** (Figure P). The drug may have a foamy appearance.
Do not shake.
Note: Inject drug within **4 hours** of mixing it.

2.11

Let Vial Sit for 60 Seconds



Figure Q

- Set the vial on a clean flat surface and **let it sit for at least 60 seconds** to allow the liquid to settle and the foaminess to go away (Figure Q).

2.12

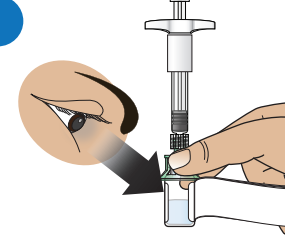


Figure R

- Once the liquid has settled, inspect the liquid (Figure R). It should be clear with slight foam, colorless, and free from visible particles.
Do not use the vial if the liquid looks colored or contains particles.

Continue On Next Page

Step 2: Reconstituting Rusfertide (PTG-300) Continued

2.13

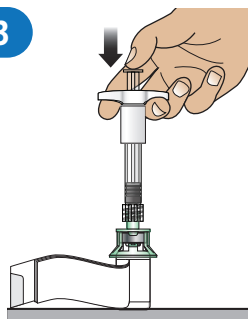


Figure S

- Make sure the plunger is pressed down all the way as the plunger may have risen up during mixing (Figure S).

2.14

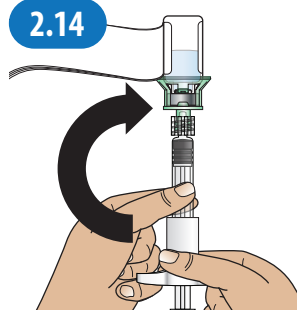


Figure T

- Turn upside down so that the PTG-300 drug vial is now on top (Figure T).

2.15

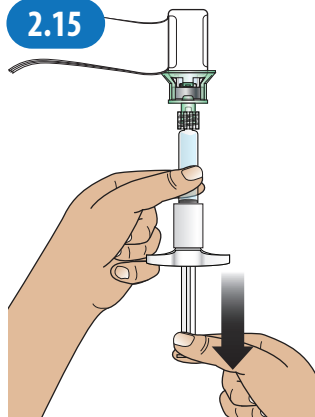


Figure U

- Draw all of the mixed drug into the syringe by slowly pulling the plunger down (Figure U). It is normal for a few drops of liquid to remain in the vial.

Be careful, do not pull the plunger rod out of the syringe.

Note: It is normal to have an air gap/bubble in the syringe after drawing liquid.

2.16

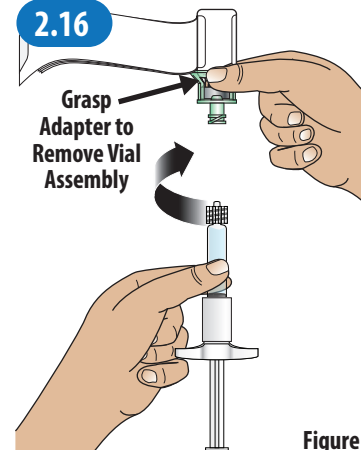


Figure V

- While holding the syringe with one hand, grasp the vial adapter and unscrew the vial assembly (vial and vial adapter) from the filled syringe by turning counter-clockwise/to the left (Figure V).

Throw away the empty vial in a sharps disposal container or as directed by the clinical site.

2.17

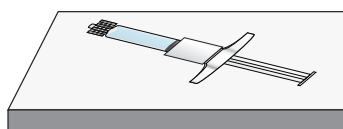


Figure W

- Set the filled syringe aside on a clean flat surface. Prevent the syringe tip from touching your hands or any surface (Figure W).

2.18

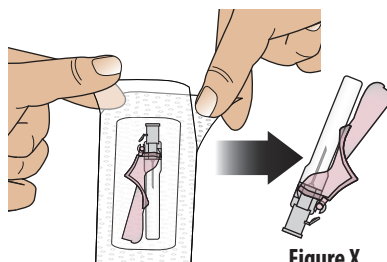


Figure X

- Remove the needle from packaging (Figure X).
Do not touch the bottom/open end of the needle.

2.19

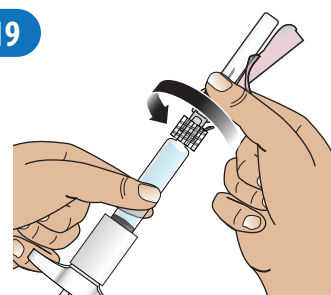


Figure Y

- Holding the syringe in one hand, screw the needle onto the syringe by turning clockwise/to the right until you feel resistance (Figure Y).

2.20

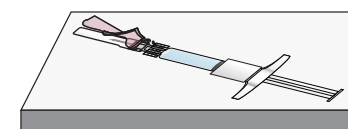


Figure Z

- Set the prepared syringe aside on a clean flat surface (Figure Z).

Step 3: Preparing The Injection Site

3.1

Front View

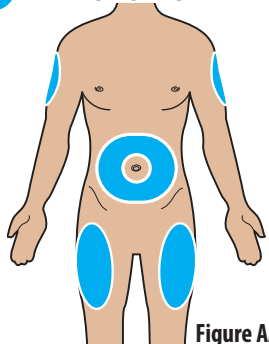


Figure AA

- Choose one of the following recommended injection sites (Figure AA):
 - **Abdomen** (at least 2 inches away from the navel [belly button])
 - **Middle area of the thigh**
 - If you are a caregiver preparing and administering the injection, you may also use the outer area of the patient's upper arm if necessary.

Do not select a site where the skin is tender, bruised, red, irritated, hard or broken.

Do not inject into the same spot twice in a row. Rotate sites between injections. If needed write down or log your injection sites.

3.2



Figure AB

- Clean the chosen injection site with a new alcohol swab (Figure AB). Throw away used swab.
- Allow to air dry.

Step 4: Injecting Rusfertide (PTG-300)

4.1

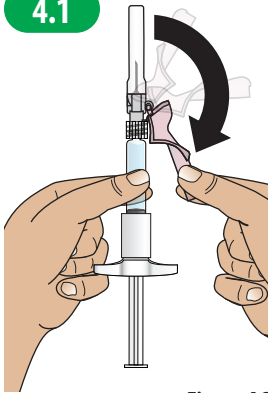


Figure AC

- Pull the pink needle shield back (Figure AC).

4.2

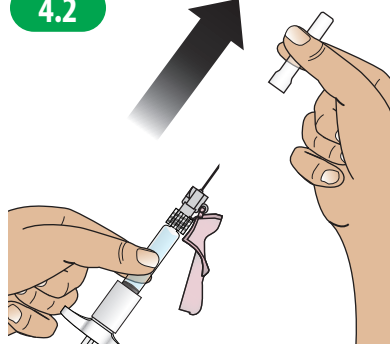


Figure AD

- Remove the needle cap by holding the syringe with one hand and **firmly pulling the cap straight off** with the other (Figure AD).
- Keep your hand moving away from the needle as you pull the cap off so you don't get stuck by the needle.

4.3

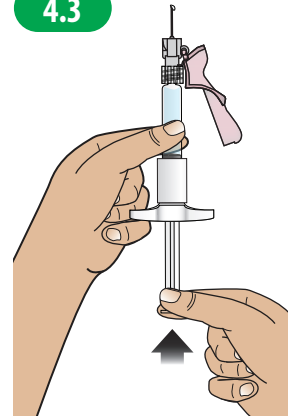


Figure AE

- **Remove air from syringe** (Figure AE). To do this:
 - Hold the syringe with the needle tip pointing straight up.
 - Tap the syringe to move any air or bubbles to the syringe tip.
 - **Slowly and carefully** push the syringe plunger to remove the air or bubbles. Stop pushing when liquid is visible at end of needle.
 - No more than 1 to 2 drops of liquid should be expelled. It is okay if a small air gap/bubble is left in the syringe.

4.4

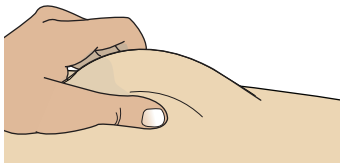


Figure AF

- Use one hand to pinch the skin at the injection site (Figure AF). This allows you to insert the needle into the fatty tissue just under the skin.

4.5

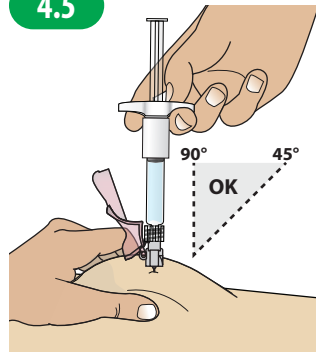


Figure AG

- Insert the needle into the pinched skin at a 90-45 degree angle (Figure AG).
- Then release the pinched skin.

4.6

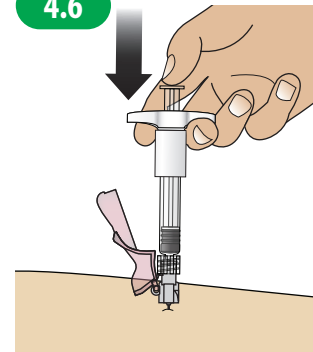


Figure AH

- **Slowly push the plunger to inject all the PTG-300 drug** (Figure AH).
- Once all liquid is injected, pull the needle and syringe out of the skin at the same angle as you inserted it.

Step 5: Disposing of Rusfertide (PTG-300)

5.1

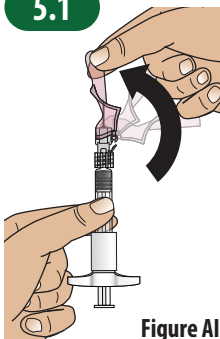


Figure AI

- Carefully push the pink needle shield over the needle until it snaps into place and covers the needle (Figure AI).

5.2

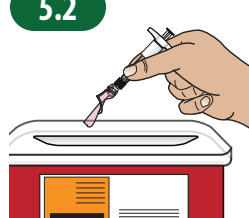


Figure AJ

- Immediately place the used syringe into the Sharps Container (Figure AJ). **Do not** throw the needle and syringe in your household trash. The needle and syringe should **NOT** be reused. Always keep the Sharps Container out of reach of children.

5.3

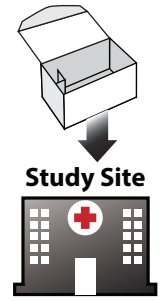


Figure AK

- **Return empty cartons to the Clinical Site** (Figure AK).
- **Throw away the empty vial in a sharps disposal container** or as directed by the clinical site.
- **Throw other materials into household trash.** Used syringe caps, used vial caps, used vial adapter caps, used alcohol swabs and opened packaging maybe be disposed of in household trash.

Additional Information

- **For additional information on how to use the PTG-300 contact the Clinical Site.**